REMARKS

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

Group I, claims 8-11, 19-21, 24, 27, 55-56 and 67-71, drawn to a method of increasing neural expression of one or more proteins on neural precursor cells in vitro

Group II, claims 34-36 and 55-58, drawn to a method of promoting growth or differentiation of neural precursor cells ex vivo

Group III, claims 46-51 and 73-74, drawn to a method for treating injury to nervous system tissue in a mammal

Responsive to the Requirement for Restriction, Applicants elect to prosecute the invention of Group III, claims 46-51 and 73-74, drawn to a method for treating injury to nervous system tissue in a mammal, with traverse.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C. §121 "two or more independent and distinct inventions ... in one Application may ... be restricted to one of the inventions." Inventions are "'independent'" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "'distinct'" means that "two or more subjects as disclosed are related ... but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under Patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

Applicants respectfully submit that the groups designated by the Examiner fail to define methods of treating injury to nervous system tissue in a mammal, and methods of promoting growth or differentiation of neural precursor cells ex vivo, with properties so distinct as to warrant separate Examination and Search. Claims 46-51 and 73-74, of elected Group III, which are drawn to a method for treating injury to nervous system tissue in a mammal, are fundamentally related to the claims of Group II, claims 34-36, and 55-58, drawn to a method of promoting growth or differentiation of neural precursor cells ex vivo, and in fact were previously examined together since they fell within the same group elected by way of the first restriction requirement.

Applicants respectfully draw the Examiner's attention to the fact that **the steps in the method claims of elected Group III, for treating injury to nervous system tissue in a mammal are virtually identical to the steps used in the method claims of Group II, for promoting growth or differentiation of neural precursor cells ex vivo using the compounds as claimed.** Furthermore, Applicants also respectfully draw the Examiner's attention to the fact that **the method of treating injury to the nervous system tissue using the compounds claimed is based on the ability of the compounds to promote growth and differentiation of neural precursor cells ex vivo, which are then delivered back to a first or second mammal.**

The Examiner alleges that Inventions I-III are directed to related processes, but are distinct if the 1)inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; 2) the inventions do not overlap in scope, ie. are mutually exclusive; and 3) the inventions are not obvious variants. The Examiner further alleges that the invention of group III can be practiced with the materially different design, mode of operation or function, for example, by transplanting integrated elongated neuronal cells, by administering CST neurotrophin to the lesion, by administering liposome containing dichloromethylene diphosphonate or by attenuating nervous system damage after injury which comprises

administering therapeutic amount of PREG, PREG-S or esters of PREG-S together with an enhancer of secretory processes in non-neuronal cells such as bacterial lipopolysaccharide and a non-steroidal anti-inflammatory substance such as indomethacin. In addition, the Examiner alleges that the inventions as claimed do not encompass overlapping subject matter.

Applicants respectfully traverse the Examiner's allegations for the following reasons and assert that **the claims of elected Group III and Group II claims do encompass overlapping subject matter and are not mutually exclusive.** As related to number 1) above, the inventions of elected Group III and Group II are certainly capable of use together, and Applicants assert that it is the neural growth and neural differentiation promoting capabilities of the currently claimed compounds that result in the ability of these compounds to be used in the methods of Group III claims for treating injury to nervous system tissue. Furthermore, with respect to number 2) above, Applicants assert that the inventions are not mutually exclusive for the following reasons. The methods of Group II result in the growth and differentiation of neuronal precursor cells *ex vivo*, and when these cells are transplanted back to a first or second mammal (as they are in the steps of the claims of both Groups II and III), they are effective for treating an injury to nervous system tissue. Stated differently, the method of treating the injury to nervous system tissue relies on the ability of these claimed compounds to induce the growth and differentiation of neural precursor cells. Without doing so, it may not be possible to treat the injury to nervous system tissue. Applicants assert that the methods of Group II claims would result in the outcome of the method of Group III claims and in addition, the method of treating nervous system injury of Group III relies on the methods of Group II. Thus, the Group III claims are not mutually exclusive of the claims of Group II. As such, Applicants assert that the claims of elected Group III should not be restricted from the claims of Group II.

Moreover, Applicants respectfully traverse the Examiner's assertion that the invention of group III can be practiced with a materially different design, mode of operation or function, for example, by transplanting integrated elongated neuronal cells, by administering CST neurotrophin to the lesion, by administering liposome containing dichloromethylene diphosphonate or by attenuating nervous system damage after injury

which comprises administering therapeutic amount of PREG, PREG-S or esters of PREG-S together with an enhancer of secretory processes in non-neuronal cells such as bacterial lipopolysaccharide and a non-steroidal anti-inflammatory substance such as indomethacin. Applicants respectfully point out to the Examiner that **the materials cited above fall outside the scope of the present invention**. None of these materials are cited in the presently claimed invention. The claims as pending are specifically directed to the use of the particular compounds as described in the specification and currently claimed.

Applicants assert that a search on the claims elected by way of the response to the restriction requirement (elected Group III, claims 46-51 and 73-74) would require a search on the characteristics of the compounds that are responsible for use in treating an injury to nervous system tissue by virtue of their ability to induce the growth and differentiation of neural precursor cells, as currently claimed in Group II (claims 34-36 and 55-58). Applicants assert that such a search would result in identification of identical subject matter.

Applicants respectfully assert that the search for any of the characteristics of the methods for treating injury to nervous system tissue in a mammal using the compounds as claimed, classified by the Examiner as the invention of Group III, would require an additional search of related material wherein the invention of Group II is classified, thus resulting in a duplicate search for the same or related material.

Thus, Applicants submit that the Search and Examination of the entire Application, or, at least, of elected Group III with Group II can be made without serious burden, and therefore the Examiner must examine all of the claims, or in the alternative, at least those of elected Groups III and II, of the Application on the merits.

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the claims of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Groups III and Group II is in order.

No fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment, or credit any overages.

In view of the above, withdrawal of the Requirement for Restriction is requested, and an early action on the merits of the claims is courteously solicited.

Respectfully submitted,

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